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510(k) Summary
[as required by 21 CFR 807.92]

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Submitter's Information [21 CFR 807.92(a)(1)]

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Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade name is Fuji FCR[®] (Fuji Computed Radiography) DMS Optical Disk Image Filing Unit OD-F6X4/L Series and Multimodality System. The Series includes models OD-F614, OD-F614L, OD-F624, OD-F624L, and Fuji Multimodality Systems. FCR[®] is a registered trademark of Fuji Photo Film Co., Ltd., Inc. The device common name optical disk file system.

Predicate Device [21 CFR 807.92(a)(3)]

Fuji identifies the predicated device as the Fuji FCR DMS OD-F623. FDA assigned the predicate Fuji FCR DMS OD-F623 to regulatory class II, with FDA product code RA 90 KPR (system, X-ray, stationary) citing 21 CFR § 892.1680.

FDA's accession number for the predicate device is K921112/B. FDA cleared the marketing of the predicate device in a letter dated April 27, 1993.

Description of the Device [21 CFR 807.92(a)(4)]

These devices store FCR (Fuji Computed Radiography) and other (for example CT and MRI) image and patient ID data on glass 12-inch (OD-F614 Series) or 5-inch OD-F624 Series optical disks using a single optical disk drive (OD-F614 or OD-F624) or optical disk library (OD-F614L or OD-F624L).

These devices are connected to FCR image reader through HI-C654 CRT image consoles, and connected to other image sources through Fuji multiformatters MF-300L. FCR images are compressed at the transmitter HI-C654 by reversible compression (compression rate: 1:2), transmitted to OD-F614 via the network, and recorded on optical disks. Images data from other modalities are compressed at the multiformatter (compression rate: 1:2), and similarly transmitted to OD-F614 via the network, and recorded on optical disks.

Patient ID data stored on the optical disks is simultaneously recorded on a magnetic disk for database retrieval. Using the database, image data can be retrieved by various criteria according to remote search requests from the image consoles (HI-C654), and transmitted to the image console where it is displayed

on the CRT as may be printed on film. The subject optical disk filing units do not monitor, control, or affect any equipment that is directly involved with the patient. The optical disk filing units do not come in contact with the patient. The optical disk filing units perform no data manipulation, but store data received from host imaging modalities.

Images stored and retrieved from the subject device are expected to be used for primary radiographic interpretation when displayed on a soft- or hard-copy device (not part of this submission). Interpretation provides adequate opportunity for competent human intervention. The level of concern associated with the function of the device is minor; failures or latent design flaws are not expected to result in injuries to patients.

Intended Use [21 CFR 807.92(a)(5)]

The subject devices share the intended use of the predicate OD-F623: the storage of FCR image with patient identification data. The subject devices add the additional capability to store image and patient identification data from sources other than computed radiography image readers.

Technological Characteristics [21 CFR 807.92(a)(6)]

The subject OD-F6X4/L Series optical disk filing units are similar in design and composition to the predicate OD-F623. The OD-F614/L Series media is 12 inch glass optical disks with improved storage characteristics. The data error rate after correction is 10^{-12} bit, equivalent to one bit in the data stored in 148 of the larger, 12-inch, 7 GB optical disks.

Performance Data [21 CFR 807.92(b)(1)]

For digital image data storage systems, the performance measure bearing on safety and effectiveness is the device's accuracy or data error rate. For the subject and predicate devices, the data error rate (after correction) is 10⁻¹² bit, equivalent to one bit in the data stored in 148 of the new, larger, 12-inch, 7 GB optical disks. ↑

Conclusion [21 CFR 807.92(b)(3)]**Conclusion [21 CFR 807.92(b)(3)]**

The Fuji OD-F6X4/L Series optical disk filing units have the same design and operating characteristics as the predicate device and, with the same data error rates, will be as safe and effective as the predicate Fuji OD-F623.